AGENDA

FOOD AND DRUG ADMINISTRATION

TRANSMISSIBLE SPONGIFORM ENCEPHALOPATHIES ADVISORY COMMITTEE

Holiday Inn
Versailles Ballrooms I & II
Bethesda, Maryland 20814
June 28 & 29, 2001

FIRST DAY, Thursday, June 28, 2001, OPEN SESSION

8:00 a.m. Administrative Remarks,
William Freas, Ph.D., Executive Secretary

8:10 a.m. Opening Remarks
David Bolton, Ph.D., Committee Chairman

TOPIC 1. Suitability of blood donors who have lived or traveled in various countries based on recent information concerning new-variant Creutzfeldt-Jakob disease (vCJD) and bovine spongiform encephalopathy (BSE)

8:20 a.m. Introduction, Charge and Questions
David M. Asher, M.D., OBRR, FDA

Estimated Potential Human Exposures to the BSE Agent in Various Countries

8:40 The Geographic BSE Risk Assessment (GBR) Conducted for the European Commission
Joachim Kreysa, Ph.D.
Scientific Steering Committee, European Commission
Brussels, Belgium

9:10 vCJD and Blood Risk Assessment, an EU Policy Position
Professor Jean-Hugues Trouvin
Director, Directorate for Evaluation of Medicinal Products and Biologicals
French Medicine Agency

9:25 Mathematical Modeling of Potential Human BSE Exposures in Various BSE Countries
Christl Donnelly, Sc.D.
Department of Epidemiology, University of London
London, UK

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TSEAC AGENDA, June 28, 2001 (continued)

BSE Exposure, Risk Reduction and Projected Effects on Blood Supply

9:45 a.m Potential Exposures to BSE of Canadian Traveler, Possible Blood and Plasma Donor Deferral policies and Projected Effects on the Canadian Blood Supply
Antonio Giulivi, M.D.
Associate Director, Bureau of Infectious Diseases,
BloodBorne Pathogens Division
Health Canada

9:55 Break

10:15 Blood Donor Deferral Options Related to Possible BSE Exposure: Risk Reduction and Estimated Blood Supply Impact in the United States
Alan Williams, Ph.D.
Director, Division of Blood Applications
Office of Blood Research and Review.
FDA, Rockville, MD

10:45 **Open Public Hearing**

11:45 Committee Discussion, Conclusions, Votes

12:45 p.m. Lunch

1:40 **Committee Update:**
Summary of DHHS Action Plan on BSE/TSE
Stephen D. Nightingale, M.D.
Executive Secretary, DHHS Advisory Committee on
Blood Safety and Availability

Topic 2. Safety of FDA-Regulated Plasma Derivatives Prepared in Establishments Proposing to Use on the Same Manufacturing Line, Plasma Which Does and Plasma Which Does Not Comply with Potential European Donor Deferrals for vCJD Risk Factors

2:00 p.m. Introduction, Charge and Questions
Dorothy Scott, M.D., OBRR, FDA

2:10 Scientific Aspects of Decontamination, Methods For Transmissible Spongiform Encephalopathies
Robert Rohwer, Ph.D.
Director, Molecular Neuro-virology Unit, VA Medical Center,
Baltimore

TSEAC AGENDA, June 28, 2001 (continued)

2:55 p.m. Industry Presentations:

vCJD Risk Assessment
Henry Baron, M.D., Senior Director of Prion Research, Aventis Behring
Considerations for Facility Cleaning
Jeff Davis, Head of Research and Development, ZLB Switzerland
Complexities of Manufacturing
Gordon Busenbark, Vice President/General Manager Hyland Immuno Plasma
Impact of vCJD measures re European Donor Deferrals
Christopher Healey, President, ABRA

3:55 Break

4:10 **Open Public Hearing**

4:40 Committee Discussion, Conclusions, Votes

6:00 p.m. Adjourn for **day 1**

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SECOND DAY, Friday, June 29, 2001, OPEN SESSION

TOPIC 3. Update: Interim results of a new study on the inactivation of TSE agent by the manufacturing process of gelatin

8:00 a.m.	FDA Introduction **Yuan Yuan Chiu, Ph.D., CDER, FDA**
8:15	European Gelatin industry, Policy and Measures Ensuring TSE Safety **Michel Schoentjes, Ph.D.** Vice President GME
8:45	Inactivation study: Overview and Results **Robert Rohwer, Ph.D.**
9:45	Break
10:00	**Open Public Hearing**
10:30	FDA Summary **John Bailey, Ph.D., CFSAN, FDA**
10:45	Committee Discussion Committee Discussion
11:45 a.m.	Adjourn